REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejection, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above amendments and remarks that follow.

Claims 31-42 have been cancelled without prejudice or disclaimer. New Claims 43-71 are presented herein. It is respectfully submitted that no new matter is introduced by this amendment. Support for the new claims may be found throughout the specification and particularly on pages 4-9 and in the original claims.

The invention, as claimed, is directed to a bone graft substitute composition comprising 100 parts by weight of calcium sulfate hemihydrate, about 1 to about 10 parts by weight of a plasticizing substance, such as a cellulose derivative or hyaluronic acid, and an aqueous mixing solution. As noted in independent Claim 43, the composition is provided in a form suitable for use as a bone graft substitute. In one embodiment, as recited in independent Claim 62, the composition is capable of being handled and shaped into a form suitable for positioning in a surgical site. In yet another embodiment encompassed by Claim 68, the composition is provided in a shape suitable for insertion into a surgical site or loaded into an injection apparatus suitable for injecting the composition into a surgical site. Claims 69-71 depend from Claims 43, 62, and 68, respectively, and are directed to a method of treating a patient having a bone defect by applying the claimed bone graft substitute composition to the site of the bone defect.

Various combinations of cancelled Claims 31-42 stand rejected as being anticipated by U.S. Patent No. 4,735,802 to Le or GB 999,487. In addition, various combinations of cancelled Claims 31-42 stand rejected as being unpatentable over either the GB 999,487 reference or the Le reference.

Although these rejections are rendered moot by cancellation of Claims 31-42, Applicants will address the relevance of these references to the presently claimed invention. Applicants note that the Le reference is directed to a topical dermatological composition comprising calcium sulfate, water and, optionally, a water soluble thickener such as sodium carboxymethyl cellulose. The Le reference suggests mixing water with calcium sulfate hemihydrate in a weight ratio of 4 parts water to about 1 part calcium sulfate, and does not disclose the amount of the optional

thickener. Thus, the Le reference clearly fails to teach or suggest the bone graft substitute composition as presently claimed. Further, Applicants note that the Le reference does not suggest use of the composition described therein as a bone graft substitute.

The GB 999,487 reference is similarly irrelevant to the presently claimed invention. The GB reference is directed to a set-retarded calcium sulfate hemihydrate composition for use as a wall plaster. Thus, the reference is clearly not directed to a composition provided in a form suitable for use as a bone graft substitute as recited in Claim 43. Similarly, the reference fails to teach or suggest a composition capable of being handled and shaped into a form suitable for positioning in a surgical site as specified in Claim 62, and further fails to teach or suggest a composition that is loaded into an injection apparatus suitable for ejecting the composition into a surgical site or formed into a shape suitable for insertion into a surgical site as recited in Claim 68. Clearly, the cited reference is in the art of wall plaster and cannot be viewed as suggesting a composition having the qualities needed for surgical use. Additionally, the cited GB reference clearly fails to teach or suggest a method of treatment as recited in Claims 69-71, or an aqueous mixing solution comprising sterile water or a cationic surface active agent as recited in Claims 50, 52-53, and 67.

It is believed that the pending claims are patentable over the art of record and formal notification of allowability is respectfully requested. It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

Christopher M. Humphrey
Registration No. 43,683

Customer No. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Raleigh Office (919) 862-2200
Fax Raleigh Office (919) 862-2260

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3/23/04 — Date